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| 10/777,415 | 02/11/2004 | Ramkumar Subramanian | ALZ5116USANP | 4311 |

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| EXAMINER | |
|---|---|
| MAEWALL, SNIGDHA | |
| ART UNIT | PAPER NUMBER |
| 1615 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/777,415 | SUBRAMANIAN ET AL. | |
| | Examiner | Art Unit | |
| | Snigdha Maewall | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-39* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## *DETAILED ACTION*

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4 and 28-29 are drawn to a **dosage form** comprising:

(a) a membrane defining a compartment, the membrane having an exit orifice formed or formable therein and at least a portion of the membrane being semi permeable;

(b) an expandable layer located within the compartment remote from the exit orifice and in fluid communication with the semi permeable portion of the membrane;

(c) a delay layer located adjacent the exit orifice;

(d) a drug layer located within the compartment between the delay layer and the expandable layer; and

(e) an interface boundary between the delay layer and the drug layer, the interface boundary being convex in shape relative to the exit orifice.

Classified in class 424 subclass 400/473/468.

II. Claims 5-7, 24-25 and 32-36 are drawn to a **dosage form** comprising:

(a) a membrane defining a compartment, the membrane having an exit orifice formed or formable therein and at least a portion of the membrane being semi permeable;

(b) an expandable layer located within the compartment remote from the exit orifice and in fluid communication with the semi permeable portion of the membrane;

(c) a delay layer located adjacent the exit orifice;

a drug layer located within the compartment between the delay layer and the expandable layer; and

(d) the delay layer having a higher viscosity than the viscosity of the drug layer when both are subjected to the same level of hydration.

Classified in class 424 subclass 400/473/468.

III. Claims 8 and 26-27 are drawn to a **dosage form** comprising

(a) a membrane defining a compartment, the membrane having an exit orifice formed or formable therein and at least a portion of the membrane being semi permeable;

(b) an expandable layer located within the compartment remote from the exit orifice and in fluid communication with the semi permeable portion of the membrane;

(c) a delay layer located adjacent the exit orifice; and

(d) a drug layer located within the compartment between the delay layer

and the expandable layer;

Classified in class 424 subclass 400/473/468.

IV. Claim 23 is drawn to a **dosage form** comprising

(a) a membrane defining a compartment, the membrane having an exit orifice formed or formable therein and at least a portion of the membrane being semi permeable;

(b) an expandable layer located within the compartment remote from the exit orifice and in fluid communication with the semi permeable portion of the membrane;

(c) a delay layer located adjacent the exit orifice;

(d) a drug layer located within the compartment between the delay layer and the expandable layer; and

(e) the major component of the delay layer having a viscosity when subjected to an aqueous medium greater than the viscosity of the major component of the drug layer in the same aqueous medium at the same level of hydration.

Classified in class 424 subclass 400/473/468.

V. Claims 9, 12-13, 16,19-22 and 38 are drawn to:

**a method** of reducing tunneling of a drug layer through a delay layer of a delayed release dosage form during a delay period, the dosage form having a compartment for containing the delay layer and the drug layer

prior to release and an exit orifice for releasing the material of the delay and drug layers, the delay layer being disposed between the drug layer and the orifice, the method comprising:

(a) formulating the delay layer and the drug layer such that the viscosity of the delay layer remains higher than the viscosity of the drug layer during the delay period.

Classified in class 424 subclass 400.

VI. Claims 10, 14, 17 and 39 are drawn to:

**a method** of controlling the release of a drug layer from a delayed release dosage form, the dosage form having a compartment for containing a delay layer and the drug layer prior to release and an exit orifice for releasing the material of the delay and drug layers, the delay layer being disposed between the drug layer and the orifice, the method comprising:

(a) formulating the delay layer and the drug layer such that the viscosity of hydrated portions of the delay layer within the compartment remains higher than the viscosity of the hydrated portions of the drug layer within the compartment during a substantial portion of the time that the delay layer inhibits the release of the drug layer from the compartment.

Classified in class 424 subclass 400/473/468/489.

VII. Claims 11, 15 and 18 are drawn to:

**a method** of controlling the release of a drug layer from a delayed release

dosage form, the dosage form having a compartment for containing a delay layer and the drug layer prior to release and an exit orifice for releasing the material of the delay and drug layers, the delay layer being disposed between the drug layer and the orifice, the method comprising: formulating the delay layer and the drug layer such that the general viscosity of the delay layer when hydrated is greater than the general viscosity of the drug layer when hydrated to the same level of hydration. Classified in class 424 subclass 400/473/468/489.

VIII. Claim 30 is drawn to:

**a method** of controlling the release via an exit orifice of delay layer materials and drug layer materials from a dosage form comprising a delay layer and a drug layer, the method comprising disposing a delay layer between the drug layer and the exit orifice with the delay layer having a viscosity higher than the viscosity of the drug layer.

Classified in class 424 subclass 400/473/468/489.

IX. Claim 31 is drawn to:

**a method** of controlling the release via an exit orifice of delay later materials and drug layer materials from a dosage form comprising a delay layer and a drug layer, the method comprising disposing a delay layer between the drug layer and the exit orifice with the principal component of the delay layer having a viscosity higher than the viscosity of the principal

component of the drug layer.

Classified in class 424 subclass 400/473/468/489.

X. Claim 37 is drawn to:

**a method** of controlling the release of a drug layer from a delayed release dosage form, the dosage form having a compartment for containing a delay layer and the drug layer prior to release and an exit orifice for releasing the material of the delay and drug layers, the delay layer being disposed between the drug layer and the orifice such that an interface exists between the drug layer and the delay layer, the method comprising: configuring the shapes of the drug layer and the delay layer such that the shape of the interface is substantially convex in relation to the exit orifice.

Classified in class 424 subclass 400/473/468/489.

2. The inventions are distinct, each from the other for the following reasons: Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01).

3. Inventions I and II -IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different mode of operation and effect. Group I requires an interface boundary, which is not required, by group II-IV. Group II requires a delay layer

with higher viscosity which is not required by rest of the groups. Group III requires a condition with respect to an aqueous medium and group IV requires limitations with respect to major component of the delay layer which is not required by rest of the groups. These limitations make inventions I through IV distinct from each other.

4. Inventions I and V –X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions differ in their modes of operation and effects. Group I is drawn to a dosage form whereas groups V-X are drawn to distinctly claimed methods comprising distinct steps.

5. Inventions II and V-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions differ in their modes of operation and effects. Group II is drawn to a dosage form whereas groups V-X are drawn to distinctly claimed methods comprising distinct steps.

6. Inventions III and V-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs,

modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions differ in their modes of operation and effects. Group III is drawn to a dosage form whereas groups V-X are drawn to distinctly claimed methods comprising distinct steps.

7. Inventions IV and V-1X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions differ in their modes of operation and effects. Group IV is drawn to a dosage form whereas groups V-X are drawn to distinctly claimed methods comprising distinct steps.

8. Inventions V and VI –X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are distinct because they vary in terms of operation and are directed to various processes.

9. Inventions VI and VII-10 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different

designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are distinct because they vary in terms of operation and are directed to various processes.

10. Inventions VII and VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are distinct because they vary in terms of operation and are directed to various processes.

11. Inventions VIII and IX-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are distinct because they vary in terms of operation and are directed to various processes.

12. Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are distinct because they vary in terms of operation and are directed to various processes.

13. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

14. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

15. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

16. Upon electing Group II applicants are further required to elect a patentably distinct species of a tricyclic amine from the following list of species from claims 33-36.

1. cyclobenzaprine
2. amitriptyline
3. imipramine
4. desipramine

16. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 32 is generic.

17. Applicant is advised that a reply to this requirement must include identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

18. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

19. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii)identification of the claims encompassing the elected invention.

20. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the

election shall be treated as an election without traverse.

21. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.IO3(a) of the other invention.

22. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the.currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-61971 The examiner can normally be reached on Monday-Friday from 8:30 A.M to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-

273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Snigdha Maewall

Art unit 1615

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